

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE COMMISSIONER OF HEALTH

In the Matter of Oak Terrace Health
Care Center of Gaylord
Survey Exit Date: April 18, 2008

RECOMMENDED DECISION

The above matter was the subject of an Independent Informal Dispute Resolution (IIDR) conference conducted by Administrative Law Judge Richard C. Luis on November 24, 2008. The conference was held at the Office of Administrative Hearings in Saint Paul, Minnesota. The record of this matter closed at the end of the conference on that date.

Marci Martinson, R.N., IIDR Coordinator, Licensing and Certification Program, appeared on behalf of the Department of Health's Division of Compliance Monitoring. Mary Cahill, Planner Principal with the Division of Compliance Monitoring, also participated in the conference.

Susan Schaffer, Attorney at Law, appeared on behalf of Oak Terrace Health Care Center of Gaylord (Oak Terrace or Facility). The following persons made comments on behalf of the Facility: Roxanne Gosson, Facility Administrator and Holly Kranz, R.N., Director of Nursing for the Facility.

FINDINGS OF FACT

1. On April 18, 2008, the Department of Health's Office of Health Facility Complaints (OHFC) conducted a standard survey at Oak Terrace Health Care Center, a nursing home located in Gaylord, Minnesota. On May 2, 2008, OHFC issued a Statement of Deficiencies ("SOD"). The SOD listed eight deficiencies of varying scope and severity levels. Three of the deficiencies were assessed at severity level G.¹

2. Oak Terrace disputes certain findings and determinations about two residents (Resident #2 and Resident #8) in the three level G deficiencies made by OHFC in its SOD. In response to the issuance of the SOD, Oak Terrace filed a Request for Independent Informal Dispute Resolution.

Resident #2

3. Resident #2 was admitted to Oak Terrace on November 28, 2007, after a fall resulted in a fracture. Resident #2 was diagnosed with osteoarthritis,

¹ MDH Ex. G.

malaise and fatigue, anemia, polymyalgia rheumatica. depression and severe aortic stenosis. From December 1, 2007, Resident #2 has had a history of black bloody stools. At that time, Resident #2 was observed to have bruising over much of her body. The test of her blood coagulants (International Normalized Ratio or INR) was measured at that time at 1.08. That INR score would fall within the expected results for anticoagulant effect.²

4. On January 22, 2008, more bruising was observed on Resident #2. No specific sources of these injuries were identified. Similar bruising was noted on January 28, 2008. The physician noted the bruising and indicated that Resident #2's condition should be followed up on in one month.³

5. On January 30, 2008, Resident #2 was complaining of headache and exhibited blood pressure of 82/53. The physician was notified at that time, but Resident #2's condition stabilized. Resident #2 often exhibited low blood pressure, attributed to her condition of aortic stenosis.⁴

6. On February 14, 2008, Resident #2's hemoglobin was measured at 10.3., She was hospitalized at Abbot Northwestern at this time due to influenza.⁵

7. On March 10, 2008, Resident #2 visited a clinic to address frequent incontinence and loose stools. As part of that review, Resident #2's physician prescribed the anticoagulant medication, Coumadin. On March 13, 2008, Resident #2 started on Coumadin at the dosage of 5 mg daily for 2 days and then 2.5 mg daily after the 5 mg dosage was complete. This regimen continued until March 31, 2008. The existing anticoagulant medication Resident #2 had been taking was discontinued when she began the Coumadin regimen.⁶

8. As part of the Coumadin regimen, the Facility staff was directed by the physician to check Resident #2's Prothrombin Time (protime or PT) and INR levels in about four days to ensure that therapeutic levels of anticoagulant were reached. On March 17, 2008, Resident #2's INR was 1.9. The physician ordered a recheck in three weeks. On March 21, 2008, Resident #2 was seen again by the physician, who ordered the Coumadin continued at the current dose. Regarding the problems Resident #2 had been having with stools, the physician diagnosed possible colostrum difficile or aggravation of diverticulitis. Bloody stool is a symptom of diverticulitis that staff were directed to watch for by the physician.⁷

9. On March 22, 2008, Resident #2 did not report any pain or discomfort. She went out with relatives the next day and reported no problems.

² Testimony of Kranz. As a general matter, the parties did not dispute the factual basis of the care provided. The testimony recited information that is drawn directly from the nursing notes and interpreted to make abbreviations and terms of art more readily understandable.

³ Testimony of Kranz.

⁴ Testimony of Kranz.

⁵ Testimony of Kranz.

⁶ Testimony of Kranz.

⁷ Testimony of Kranz.

Resident #2's blood pressure was checked upon her return to the facility and it was 87/56, which was low, but within Resident #2's normal range. Staff continued to monitor for the problems previously identified.⁸

10. On March 25, 2008, Resident #2 did have bloody mucus on her bed pad. Another stool sample was sent to the lab for analysis. Resident #2's stool was dark but not bloody. No complaints of pain or discomfort were made by Resident #2 at that time.⁹

11. On March 26, 2008, Resident #2's condition was observed to be normal, with no fever and no diarrhea. The *C. Difficile* test results were returned as positive, meaning that Resident #2 did have signs of a possible infection of the colon caused by bacteria that can follow the use of antibiotics. Such an infection can cause a form of colitis. Resident #2's physician prescribed Flagyl in response to the *C. Difficile* test results.¹⁰

12. On March 27, 2008, Resident #2 was started on Flagyl, administered three times per day with the medication to run for two weeks. No complaints of pain or discomfort were made by Resident #2 at that time. No unusual discharges or other problems were observed.¹¹

13. On March 28, 2008, Resident #2 was observed at 7:00 a.m. with blood in her mouth. Upon examination by an L.P.N. from the Facility's nursing staff, the blood in Resident #2's mouth was determined to coming from a sore. On her leg near the ankle, she had a skin tear leaking blood with a 7 cm bruise surrounding the tear (suggesting she had bumped her ankle to cause the injury). The L.P.N. dressed and bandaged the injury. Resident #2 could not recall how she suffered that injury. When family members visited that morning they were informed of the situation. The Facility staff offered to have Resident #2 seen by a physician at that time. The family members (including one who is an R.N. who worked for the Facility) indicated that faxing the information to the physician was sufficient. There were no indications that Resident #2 was in any distress on the morning of March 28, 2008. Resident #2's physician was notified of these conditions by fax at 11:30 a.m. Facility staff instituted salt water rinses to address the observed sore in Resident #2's mouth.¹²

14. On March 29, 2008, Resident #2 had the ankle wound dressing replaced. Staff noted there was drainage on the dressing from a skin tear. The drainage had dried on the dressing and the dressing needed to be soaked to remove it from Resident #2's ankle. The nursing staff observed Resident #2's mouth to follow up on the observation from the prior day. No bleeding from her mouth was noted. Salt water rinses were continued to address the observed sore.¹³

⁸ Testimony of Kranz.

⁹ Testimony of Kranz.

¹⁰ Testimony of Kranz.

¹¹ Testimony of Kranz.

¹² Testimony of Kranz.

¹³ Testimony of Kranz.

15. On March 30, 2008, Resident #2's culture results were returned that ruled out parasites, salmonella, or shigellosis. Those results were faxed to Resident #2's physician. No other problems were observed regarding Resident #2's condition.¹⁴

16. On March 31, 2008, nursing staff noted that Resident #2 had two black and bloody stools with blood in toilet. At 9:50 a.m., the on-call physician was notified. The on-call physician reviewed Resident #2's condition. Based on that review, the physician ordered Coumadin and aspirin stopped and that Resident #2 have a blood count taken. The physician also ordered that a Protime/INR test be performed the next morning. The physician instructed that she should be called back if further bloody stool was observed. The physician indicated that Resident #2's regular physician should be updated with the results the next day. A family member was also contacted about Resident #2's condition.¹⁵

17. In the morning on March 31, 2008, Resident #2's vital signs were blood pressure 77/47 and pulse 63. Resident #2 was alert and oriented with no dizziness, headaches, or pain. A nursing note entry was made at 2 p.m. when the nursing staff checked Resident #2's mouth and found no bleeding. The note also indicated that Resident #2 "had 1 black/bloody stool shortly after talking with ... (on call physician)." Resident #2's blood pressure was 93/55 and nursing staff noted that they should continue to monitor Resident #2 for further loose or black stools and update the on-call physician if it continues. At 3:15 p.m. the nursing note indicated that Resident #2 had a large formed bloody-looking stool. The on-call physician was called and that physician called back at about 4:00 p.m. to have Resident #2 transferred to hospital. Oak Terrace staff called 911 for transport.¹⁶

18. Resident #2 was transported to the hospital by ambulance where she was admitted. The emergency room physician noted Flagyl had been started. Resident #2 was diagnosed with clostridium difficile infection, urosepsis and a gastrointestinal bleed. Blood testing done at the hospital indicated that the Resident #2's INR level was 17 and hemoglobin was 10. Resident #2 exhibited normal blood pressure at the hospital and she had no complaints of pain or discomfort.¹⁷

Resident #8

19. Resident #8 was admitted to Oak Terrace on May 25, 2006. His diagnoses included depression, hypertension, history of cerebral vascular accident, atrial fibrillation, congestive heart failure, and gastrostomy. Resident #8 was placed on Coumadin on February 6, 2008, at a dosage of 5 mgs daily. This dosage was increased on February 20, 2008 to 6 mg. Resident #8 was on Dilantin, 300 mg. The Dilantin (Phenytoin) was administered at 8 AM daily from

¹⁴ Testimony of Kranz.

¹⁵ Testimony of Kranz.

¹⁶ Testimony of Kranz.

¹⁷ Testimony of Kranz.

the time of his admission. In addition, he received Paxil, an antidepressant, 20 mg per day.¹⁸

20. The Facility nursing notes for Resident #8 reflect the following chronology of events in his care:

Date	Lab & Follow-up
1/18/08	INR 1.3 PROTINE 12.9
1/24/08	INR 1.6 PROTINE 15.3
2/6/08	INR 1.4 PROTINE 13.3
2/13/08	INR 1.8 PROTINE 16.9
2/20/08	INR 1.7 PROTINE 15.9
2/27/08	INR 2.3 PROTINE 21.2
3/13/08	INR 3.8 PROTINE 34.3 Oak Terrace Nurse faxed lab and med sheets to New Ulm Medical Center Clinic (4 pages, including med sheets) Physician order for Coumadin 5 mg. on M & F, 6 mg all other days. Re[check] 4/3. Physician also wrote to "fax med sheets on date of draw."
4/3/08	INR 7.0 PROTINE 60.7 1:15 PT results faxed to Dr. Seivert. 2:50 Left with wife Marilyn, for getting eye glasses fixed. 4:00 Call placed to Coumadin clinic to inquire about INR fax — left message. 8:00 [NO] return call from coumadin clinic, [no] fax return. Coumadin held due to critical high PT/INR. 10:00 Fax sent to coumadin clinic with PT/INR results & medication sheets.
4/4/08	10 AM — Fax returned from the coumadin clinic. See new orders to hold

¹⁸ Testimony of Kranz.

	coumadin & redraw PT/INR on Monday, 4/7/08, call placed to SMC-Gaylord — lab appt scheduled for 4/7/08 at 8:45 AM.
4/7/08	INR 1.3 PROTINE 12.4. ¹⁹

21. The Coumadin clinic is operated as an adjunct to New Ulm hospital. The Coumadin clinic is not open in the evening or overnight.²⁰

22. The increased PT/INR levels that Resident #8 experienced on April 3, 2008 did not result in any adverse health impact to him. No medical intervention was required and Resident #8 did not exhibit any symptom or condition that would suggest a need for medical intervention.²¹ Resident #8's condition was deemed sufficiently stable by the responsible medical authority that Resident #8 was not directed to be retested for PT/INR levels until the third day after the report of the increased level.

23. Upon being notified of the results of the Resident #8's situation, the Facility's Director of Nursing prepared an update of the Facility's policy that would expressly address Coumadin issues.²²

24. The Facility's Consulting Pharmacist assessed the potential impact of Resident #8's medications and concluded that "the combination of these medications had been occurring for a number of months and thus any enzymatic activity of the cytochrome P-450 system would no longer be relevant."²³ The Facility's pharmacist concluded, based on a review of the relevant professional literature, that there was no drug interaction between Resident #8's medications that would cause the change to Resident #8's INR score.²⁴

25. The system in place for notifying the responsible prescribing authority of changes in patient condition was deficient in that there was no mechanism to promptly address the known unavailability of staff at the Coumadin clinic. This deficiency was part of a pattern, but did not result in actual harm. The deficiency had the potential for more than minimal harm. The proper scope and severity level for the deficiency is level E.²⁵

Survey

26. The OHFC conducted a standard survey of the Facility that concluded on April 18, 2007. The survey team reviewed residents' medical records, conducted interviews, and examined Facility documentation relating to a

¹⁹ Facility Ex. R8-F through P.

²⁰ Testimony of Kranz.

²¹ Testimony of Kranz.

²² Testimony of Kranz.

²³ Facility Ex. R8-B.

²⁴ *Id.*

²⁵ SOM, Section 7400E1 (<http://www.cms.hhs.gov/manuals/downloads/som107c07.pdf>).

number of residents, including Resident #2 and Resident #8.²⁶ The interviews did not discuss Resident #2.²⁷

27. Survey team members informed Facility staff that seven deficiencies were identified for which F-tags would be issued. These F-tags were assigned severity levels of B (two tags), D (three tags), and E (two tags). Members of the survey team were complimentary regarding the care that was provided in the Facility.²⁸

28. At the conclusion of the visit, OHFC staff conducted an exit interview where seven deficiencies were identified, each listed as an F-tag. The deficiencies ranged from severity levels B to E.²⁹ The F-157 tag, regarding physician notification, was identified as severity level E.

29. In the week following the survey, several telephone conversations took place between staff at OHFC and Oak Terrace. Oak Terrace was informed that another deficiency was being added at severity level G and two of the earlier deficiencies were being increased to severity level G.³⁰

30. On May 2, 2008, OHFC issued its SOD identifying eight deficiencies, three of them at severity level G. One G level tag (F 309) had not been discussed at the exit conference.³¹

31. Some of the appealed tags were supported by deficiencies found regarding residents where the findings were not appealed. In those instances, the scope and severity level of the overall tag cannot be changed. The appropriate action in those instances is to modify the findings with regard to those tags.

Based upon the exhibits submitted and the arguments made and for the reasons set out in the Memorandum that follows, the Administrative Law Judge makes the following:

RECOMMENDED DECISION

The citation with regard to Tag F 157 is supported by the facts as to Resident #8, but the scope and severity level is properly assigned to level E. The citation with regard to Tag F 157 is not supported by the facts as to Resident #2 and findings in that regard should be deleted. The citation regarding Tag F 309 is not supported by the facts and should be deleted. The portion of the citations with regard to Residents #2 and #8 in Tag F 329 are not supported by the facts and the findings should be deleted with regard to those two residents.

²⁶ Testimony of Gossen.

²⁷ Testimony of Kranz.

²⁸ Testimony of Gossen.

²⁹ Testimony of Gosson.

³⁰ Testimony of Gosson.

³¹ Testimony of Gosson.

Dated: December 10, 2008.

/s/ Richard C. Luis

RICHARD C. LUIS
Administrative Law Judge

Reported: Digitally recorded (no transcript prepared).

NOTICE

In accordance with Minn. Stat. § 144A.10, subd. 16(d)(6), this recommended decision is not binding on the Commissioner of Health. As set forth in Department of Health Information Bulletin 04-07, the Commissioner must mail a final decision to the Facility indicating whether or not the Commissioner accepts or rejects the recommended decision of the Administrative Law Judge within 10 calendar days of receipt of this recommended decision.

MEMORANDUM

Scope of Review in IIDR Proceedings

OHFC maintains that the Facility cannot challenge the scope and severity level of the deficiencies found in the survey, unless a monetary penalty is affected by the appeal. The Facility points out that the state law governing the IIDR process explicitly allows challenges to scope and severity.

The Minnesota Department of Health described the ALJ findings in the IIDR process in an informational bulletin as follows:

The findings shall be one or more of the following:

Supported in full. The citation is supported in full, with no deletion of findings and no change in the scope or severity assigned to the deficiency citation.

Supported by substance. The citation is supported, but one or more findings are deleted without any change in the scope or severity assigned to the deficiency.

Deficient practice cited under wrong requirement of participation. The citation is amended by moving it to the correct requirement of participation.

Scope not supported. The citation is amended through a change in the scope assigned to the citation.

Severity not supported. The citation is amended through a change in the severity assigned to the citation.

Not deficient practice. The citation is deleted because the findings did support the citation or the negative resident outcome was unavoidable.

The findings of the ALJ are not binding on the commissioner.³²

According to the Department description of this process, both the scope and severity of deficiencies are at issue in these proceedings. The ALJ findings must reflect the record as to whether the deficiency is supported, and if so, what is the appropriate scope and severity rating. This description is nearly identical to the provisions of Minn. Stat. § 144A.10 subd. 16(d). OHFC has not cited any authority that overrides the requirements of State law in the IIDR process.

The OHFC position appears to be based on 42 CFR § 498.3, which describes issues appealable before an ALJ as:

(14) The level of noncompliance found by CMS in a SNF or NF but only if a successful challenge on this issue would affect—

(i) The range of civil money penalty amounts that CMS could collect (The scope of review during a hearing on imposition of a civil money penalty is set forth in §488.438(e) of this chapter); or

(ii) A finding of substandard quality of care that results in the loss of approval for a SNF or NF of its nurse aide training program.³³

This provision applies to appeals where CMS (or where authorized, the State agency) has issued a determination resulting in a civil money penalty (CMP) or determination of ineligibility for continuation as an authorized care provider. No such determination is made at this stage in the IIDR process. The formal appeal process is set out in Section 7303 of the SOM. Limitations to the formal appeal process were described in a recent administrative appeal which stated:

A long-term care facility **against which CMS has determined to impose a CMP** is entitled to a hearing before an ALJ. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g);498.3(b)(13). A hearing before an ALJ is a de novo proceeding. *Anesthesiologists Affiliated, et al., DAB CR65 (1990), aff'd, Anesthesiologists Affiliated, et al. v. Sullivan, 941 F.2d 678 (8th Cir. 1991)*. **The facility has a right to appeal a “certification of noncompliance leading to an enforcement remedy.”** 42 C.F.R. § 488.408(g)(1);

³² Information Bulletin 04-07 NH-98 (May, 2004) (http://www.health.state.mn.us/divs/fpc/profinfo/ib04_7.html).

³³ 42 CFR § 498.39(b)(14).

see also 42 C.F.R. § 488.330(e). However, **the choice of remedies by CMS or the factors CMS considered in choosing remedies are not reviewed.** 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the CMP amount that could be collected by CMS or impact upon the facility's NATCEP [Nurse Aide Training and Competency Evaluation Program]. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of IJ [immediate jeopardy]. Woodstock Care Center, DAB No. 1726, at 9, 38 (2000), aff'd, Woodstock Care Center v. Thompson, 363 F.3d 583 (6th Cir. 2003). The DAB has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an IJ determination. See, e.g., Ridge Terrace, DAB No. 1834 (2002); Koester Pavilion, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).³⁴

The limitations on appeals of CMS decisions are reasonable, especially since facilities are able to dispute scope and severity assessments through the IIDR process. Imposing such a limitation at this stage of the proceedings is contrary to State law and would undermine the existing CMS appeal structure.

Matters Disputed

There is no dispute that the exit conference is not final until after the final written report is issued. The Facility disputes the findings arrived at through the survey and the three G-level tags issued based on those findings with regard to Residents #2 and #8.

Tag F 157

Tag F 157 is based upon an alleged violation of 42 C.F.R. § 483.10(b)(1). That provision requires that:

A facility must Immediately inform the resident; consult with the residents physician; and if known, notify the residents legal representative or an interested family member when there is an accident involving the resident which results in injury and has the potential for requiring physician intervention; a significant change in the resident's physical, mental, or psychosocial status (i.e. a deterioration in health, mental, or psychosocial status in either life

³⁴ In the Case of Green County Care Center v. Centers for Medicare & Medicaid Services, Department of Health and Human Services Docket No. C-08-67, DAB Decision No. CR1716, at 3-4 (December 19, 2007) (<http://www.hhs.gov/dab/decisions/CR1716.pdf>) (emphasis added).

threatening conditions or clinical complications); a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or a decision to transfer or discharge the resident from the facility as specified in §483.12(a).³⁵

OHFC did not dispute the Facility's recounting of the care provided to Resident #2. The OHFC position on Resident #2 was that the concurrent administration of Coumadin and Flagyl, together with the bleeding experienced from her ankle injury created a situation where the Facility "should have made sure that the physician was informed."³⁶ This position is based on the perception that Resident #2 was at some sort of risk due to her anticoagulant medications. This position would have some merit if Resident #2 was showing signs of bleeding without an external cause. All of the bleeding exhibited by Resident #2 was attributable to either a sore (mouth) or an accidental injury (ankle). In both instances, there was an external cause and the actions taken to address the bleeding, salt rinses (mouth) and bandaging (ankle) were effective.

OHFC asserts that the Facility had an obligation to ensure that a physician was contacted and the Facility could not involve Resident #2's family in the decision-making process. The situation presented to the Facility and Resident #2's family was not of a nature to require physician intervention. The Facility had provided the care needed to address Resident #2's explained bleeding. The level of care required did not rise to the level that would cause a reasonable person to think that anything more than informing Resident #2's physician of changes was needed. The absence of any situation needing a response by a physician made faxing the information reasonable.

For Resident #2, the Facility notified the resident, resident's physician, and resident's family on the morning that the injury was first observed. The injury did not require physician intervention. Because Resident #2 was taking anticoagulant medications, there was a potential for physician intervention. Faxing the physician with Resident #2's updated condition was sufficient notification under the C.F.R. requirement.

OHFC maintains that there was some further obligation to follow-up with the physician. There were no symptoms arising from either the mouth sore or the ankle injury that in any way triggered a clinical concern as to Resident #2's anticoagulant medications. The symptom (bloody stool) which triggered the further contact with Resident #2's physician, first occurred two days later. The Facility responded appropriately at that time. There was no actual harm arising out of the Facility's action in notifying Resident #2's physician. There is no factual basis for finding a deficiency for that resident under F 157.

³⁵ 42 C.F.R. § 483.10(b)(1).

³⁶ Testimony of Martinson.

For Resident #8, the Facility recognized that the measured PT/INR was higher than appropriate. The Facility made multiple efforts to notify either the Coumadin clinic or Resident #8's physician. When those efforts failed to get a response, the Facility nursing staff acted to protect Resident #8's health by withholding the prescribed Coumadin.

The efforts to contact the responsible prescribing authority were consistent with the Facility's existing protocol, but that protocol did not take into account the limitations of resources in the area. The Facility was aware of the limited resources in the area and of the need for better communication. This constitutes a deficiency that falls under the scope of a pattern (since any resident using the Coumadin clinic would be affected). The deficiency did not rise to the level of actual harm, since variations in PT/INR test results of the sort shown by Resident #8 are not intrinsically harmful (or even unusual) and the Facility acted promptly to address the elevated PT/INR results. The severity level meets the potential for more than minimal harm. Level E is the appropriate scope and severity standard for this deficiency.

Tag F 309

Tag F 309 is based upon an alleged violation of 42 C.F.R. § 483.25. That provision requires that:

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.³⁷

OHFC maintains that the Facility was deficient in this standard due to a failure to monitor Residents #2 and #8 with respect to their anticoagulant medications. Specifically regarding Resident #2, OHFC maintains that her plan of treatment needed to be adjusted to reflect the addition of Flagyl to her medication regimen. The objection was focused on the Facility's use of a fax for notification on March 28, 2008.

OHFC cited the risks of Coumandin, particularly the warning for "unusual bruising (bruises that develop without known cause or grow in size)" as evidence that actual harm was occurring to Resident.³⁸ The Facility responded that the presence of a skin tear in the middle of the bruising on Resident #2's ankle renders this bruising different from the cited concern. The presence of the skin tear indicated that the bruising occurred through some form of external cause, not arising from a dangerous drug interaction. The effectiveness of the treatment provided to both the sites of observed bleeding (mouth and ankle) is further

³⁷ 42 C.F.R. § 483.25.

³⁸ MDH Ex. K-1.

evidence that there was no failure to meet the cited standard. There is no factual basis for finding a deficiency for Resident #2 under F 309.

Regarding Resident #8, the only monitoring that was required was the PT/INR test given on April 3, 2008. The results of that testing was faxed, by the physician's instruction, to the Coumadin clinic. There was no further monitoring called for, since the next day the Coumadin clinic directed that a retest be performed on April 7, 2008. The Facility fully met its obligation to monitor the medication being given to Resident #8. There is no factual basis for finding a deficiency for Resident #8 under F 309.

Tag F 329

Tag F 329 is based upon an alleged violation of 42 C.F.R. § 483.25 (l). That provision requires that:

Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used in excessive dose (including duplicate therapy); or for excessive duration; or without adequate monitoring; or without adequate indications for its use; or in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or any combinations of the reasons above.

Based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

OHFC cited numerous portions of the State Operations Manual in support of the contention that Oak Terrace was deficient in the standards for administration of unnecessary drugs. These standards all reflect the Facility's obligation to monitor residents receiving medications for drug interaction or negative effects arising from the medication.³⁹

OHFC maintains that the Facility was deficient regarding this standard with respect to Resident #2 because she "was hospitalized on 3/31/08 with a level of Protime of 169 and INR of 17 and experienced harm because of inadequate monitoring of another drug added to the drug regime on 3/25/08 identified to increase the toxic effects of Coumadin."⁴⁰ OHFC made a factual error in the date the second medication was started (March 27, 2008).

³⁹ MDH Ex. F.

⁴⁰ MDH Ex. G-22.

Oak Terrace noted that pharmaceutical reference works indicate the need for increased monitoring of anticoagulant effects when Coumadin and Flagyl are used together. There is no accepted monitoring regimen for anticoagulants due to the variety of factors involved. The timing of such laboratory testing is a matter of clinical opinion between practitioners and differs for different patients.⁴¹

There were no signs of drug interaction from which to conclude that any further physician intervention was needed to care for Resident #2 from March 27, 2008, until March 31, 2008. As discussed above, Resident #2's mouth and ankle bleeding were observed to have external causes and they responded to the care given. On March 31, 2008, Facility staff recognized the symptoms of a potential drug interaction (bloody stools) and took prompt and effective measures to notify Resident #2's physician and transport Resident #2 to a hospital for closer observation. There is no factual basis for concluding that the Facility's care of Resident #2 was deficient. Tag F 329 regarding Resident #2 is not supported.

OHFC maintains that the Facility was deficient regarding this standard with respect to Resident #8 because of his "critically high blood test results and the facility failed [to] notify the physician in a timely manner nor provided evidence of a medication regime review to identify the potential for increased bleeding time because of concomitant use of several medications Resident #8 had been getting in combination with the Coumadin, known to have the potential to increase the clotting time of Coumadin resulting in harm."⁴²

The Facility has demonstrated that it conducted the testing according to the prescribed schedule. The Facility acted promptly when an elevated PT/INR result was returned. The Facility retested according to the direction provided by the responsible prescribing authority. The Facility has shown that there is no factual support for a claim of drug interaction regarding Resident #8. There is no factual basis for the claimed deficiency arising from either a drug interaction or excessive dosage of Coumadin.

Conclusion

Based upon the record as a whole, the Administrative Law Judge concludes the OHFC has demonstrated that only one cited deficiency is supported by the facts. That citation was supported by the facts at a scope and severity level of E. Accordingly, it is recommended that Tag F 157 be AFFIRMED with a modification of the scope and severity level to E regarding Resident #8. It is appropriate to adjust the remaining findings and tags as indicated above.

R.C.L.

⁴¹ Testimony of Kranz.

⁴² MDH Ex. G-25.